510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical
Address:	14901 DeVeau Place
	Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	1-800-328-3873
Fax Number:	(952) 930 - 9481
Contact Person:	Glenn Jacques
Date Submission Prepared:	September 23, 2005

B. Device Information

Trade Name:	Swartz™ Braided Transseptal Guiding Introducer
Common or Usual Name:	Transseptal Catheter Introducer
Classification Name:	Catheter Introducer (per 21CFR 870.1340)
Predicate Devices:	Fast-Cath™ (Two-Piece AMAS) Transseptal Catheter Introducers (K964518)
	Agilis™ Steerable Catheter Introducer (K042623)
Device Description:	The Swartz™ Braided Transseptal Guiding Introducer set consists of a fixed compound curve, dilator, and guidewire. The fixed curve Swartz introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The introducer features distal vent holes to facilitate aspiration and minimize cavitation, and a radiopaque tip marker to improve fluoroscopic visualization. The device is provided sterile and is intended for single-use only.
Intended Use:	The St. Jude Medical Transseptal Catheter Introducer Set is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Swartz™ Braided Transseptal Guiding Introducer are substantially equivalent to the predicate devices including product design, packaging, biocompatibility, sterilization, and labeling. Where dimensional and material differences exist between the proposed device and the predicate devices, mechanical testing demonstrated that these differences do not adversely affect safety and effectiveness.

D. Support of the Substantial Equivalence

St. Jude Medical considers the Swartz™ Braided Transseptal Guiding Introducer to be substantially equivalent to the predicate devices, Fast-Cath™ (Two-Piece AMAS) Transseptal Catheter Introducer and the Agilis™ Steerable Catheter Introducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

St. Jude Medical
c/o Mr. Glenn Jacques
Regulatory Affairs Manager
14901 Deveau Pl.
Minntonka, MN 55345

Re: K052644
Swartz™ Braided Transseptal Guiding Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: September 23, 2005
Received: September 26, 2005

Dear Mr. Jacques:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K052644

Device Name: Swartz™ Braided Transseptal Guiding Introducer

Indications for Use: The St. Jude Medical Transseptal Catheter Introducer Set is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052644